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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,172	08/29/2005	Shinji Okano	50026/052001	2033
21559	7590	09/07/2007	EXAMINER	
CLARK & ELBING LLP			POPA, ILEANA	
101 FEDERAL STREET			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,172	<b>Applicant(s)</b> OKANO ET AL.	
	<b>Examiner</b> Ileana Popa	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-15,17 and 19-21 is/are pending in the application.  
4a) Of the above claim(s) 10,12,13,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,9,11,14,15,17 and 19 is/are rejected.
- 7) ☒ Claim(s) 9,11, and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/17/2007 has been entered.

2. Claims 3-8, 16, and 18 have been cancelled. Claims 10, 12, 13, 20, and 21 have been withdrawn. Claims 1, 11, 14, 15, and 17 have been amended.

Claims 1, 2, 9, 11, 14, 15, 17, and 19 are under examination.

3. All rejection pertaining to claims 3-8, 16, and 19 are moot because Applicant cancelled the claims in the response filed on 07/17/2007.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1, 2, 9, 11, 14, 15, 17, and 19 under 35 U.S.C. 112, first paragraph, as introducing new matter, is withdrawn in response to Applicant's amendment to the claims filed on 07/17/2007.

***Claim Rejections - 35 USC § 102***

5. Claims 1, 2, 9, 11, 14, 15, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu *et al.* (Genes to Cells, 1997, 2: 457-466, of record7), as evidenced by Mauri-Hellweg *et al.* (J Immunol, 1995, 155: 462-472).

Yu *et al.* teach using a Sendai virus vector encoding for gp120 to transduce a variety of cells, such as PBMCs that are stimulated with phytohemagglutinin; it is noted that the method that produces the PMBC results in a population of cells, including T-cells, wherein the T-cells necessarily comprise CD8<sup>+</sup> T-cells (see Mauri-Hellweg *et al.*, p. 468, column 1, first full paragraph, p. 470, Fig. 7); therefore, the PBMCs of Yu *et al.* must necessarily comprise activated CD8<sup>+</sup>-T cells (claims 1, 2, and 14) (Abstract, p. 460, column 2 and Table 1, p. 464, column 1, last paragraph). With respect to the limitation of the CD8<sup>+</sup>-T cells being antigen-stimulated (claims 9, 11, and 19), the protein of Yu *et al.*, i.e., phytohemagglutinin, is an antigen. With respect to the limitation recited in claim 15, it is noted that the phytohemagglutinin-activated PBMCs necessarily include co-existent naïve CD8<sup>+</sup>-T cells, wherein the naïve CD8<sup>+</sup>-T cells are not efficiently transduced. With respect to a method of enhancing transduction efficiency in CD8<sup>+</sup>-T cells, the method of Yu *et al.* must necessarily result in enhanced transfection efficiency since it involves activation of CD8<sup>+</sup>-T cells before contacting them with the Sendai virus vector. Since Yu *et al.* teach a method of transducing a gene into activated T cells by contacting the activated T cells with a paramyxovirus vector carrying the gene, wherein the paramyxovirus vector is a Sendai virus vector, the claimed invention is anticipated by the above-cited art.

Applicant traversed the instant rejection on the grounds that Yu *et al.* do not anticipate the claims, as amended. Applicant points out that, for CD8<sup>+</sup> T-cells to become activated, they must be exposed to particular stimuli. Applicant argues that Yu *et al.* neither teach nor suggest that such stimuli are present or that the PBMCs contain a subset of activated CD8<sup>+</sup> T-cells. Applicant argues that an assertion that PBMCs of Yu *et al.* inherently include activated CD8<sup>+</sup> T-cells would not be based on any evidence of record and would constitute speculation. Applicant argues that, without evidence showing that PMBCs necessarily include activated CD8<sup>+</sup> T-cells, there is no basis for an anticipation rejection based on inherency. Therefore, Applicant requests the withdrawal of the rejection.

Applicant's arguments are acknowledged, however, the rejection is maintained because Yu *et al.* do teach transduction of activated CD8<sup>+</sup> T-cells (see above).

### ***New Rejections/Objections***

#### ***Claim Objections***

6. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 recites a method comprising the step of stimulating the T-cells with an antigen. However, claim 9, from which claim 11 depends, already recites that the activated T-cells are antigen-activated.

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7. Claims 9, 11, and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 1 and 17 recite CD8<sup>+</sup> T-cells, whereas their dependent claims 9, 11, and 9 recite the broader limitation of T-cells.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 14 reciting an activated CD8<sup>+</sup> T-cell is drawn to non-statutory subject matter. Since the claim do not recite that the activated CD8<sup>+</sup> T-cell is isolated, the scope of the claims encompasses a human being carrying the activated CD8<sup>+</sup> T-cell, and human beings are non-statutory subject matter. Amending the claim to recite "isolated" would obviate this rejection.

10. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph Woitach/  
Joseph Woitach  
SPE 1633